

## **REMARKS**

Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested.

### **I      Status Of The Claims**

Claims 76-82, 84-88 and 90-98 have been canceled without prejudice. To clarify the claimed subject matter, new claims 99-128 have been added. The new claims are directed to methods of treatment using milnacipran in combination with various additional specific agents. Claims 99-108 are directed to methods of treating fibromyalgia syndrome, claims 109-118 are directed to methods of treating chronic fatigue syndrome and claims 119-128 are directed to methods of treating pain. Claims 99-108 correspond, in part, to previous claim 95, claims 109-118 correspond, in part, to previous claim 90 and claims 119-128 correspond, in part, to previous claim 84. The chemical name “gabapentin” replaces the corresponding trade name “neurontin” in claims 99, 100, 109, 110, 119 ands 120. No new matter has been added. New claims 99-108 do not raise any new issues of patentability and do not require any additional searches to be performed.

Claims 99-128 are pending in this application and are at issue.

### **II      Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 76, 88, 90, 94 and 95 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner objects to the phrase “and/or physiological symptoms associated therewith.”

Claims 76, 88, 90, 94 and 95 have been canceled, rendering this rejection moot. Accordingly, the rejection has been overcome and should be withdrawn. New claims 99-128 do not contain the phrase “and/or physiological symptoms associated therewith.” Applicants believe that new claims 99-128 comply with the written description requirement of 35 U.S.C. § 112, first paragraph

Claims 76-82, 84-88 and 90-98 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner asserts that the disclosure lacks a written basis for the

negative limitation recited in claim 76. Claims 76-82, 84-88 and 90-98 have been canceled, rendering this rejection moot. Thus, the rejection has been overcome and should be withdrawn. New claims 99-128 do not contain a negative limitation. Applicants believe that new claims 99-128 comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

### **III      Double Patenting Rejections**

Claims 76-82, 84-88 and 90-98 stand rejected for non-statutory obviousness-type double patenting over (i) claims 1-6 of U.S. Patent No. 6,992,110 (“the ‘110 Patent”), (ii) claims 1-7, 9-17 and 19-20 of co-pending Application No. 11/535,237 (“the ‘237 Application”), (iii) claims 1-25 of co-pending Application No. 11/752,213 (“the ‘213 Application”) in view of Hitzig (U.S. Patent No. 5,685,955, “Hitzig”), and (v) claims 1-11 of co-pending Application No. 11/835,620 (“the “620 Application”) in view of Hitzig.

In order to further prosecution of this application, submitted herewith are Terminal Disclaimers over the ‘110 Patent and the ‘237, ‘213 and ‘620 Applications. The rejections have therefore been obviated and should be withdrawn.

### **IV      Rejections Under 35 U.S.C. § 103**

Claims 76-82, 85-88 and 91-93 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,441,038 (“Loder”) in view of U.S. Patent No. 5,685,955 (“Hitzig”). On the basis of these references, the Examiner contends that it would have been *prima facie* obvious to combine milnacipran with amphetamine, trazadone and a sedative to treat pain perception associated with fibromyalgia and chronic fatigue syndrome.

Claims 76-82, 85-88 and 91-93 have been canceled, rendering this rejection moot. New claims 99-128 do not recite amphetamine or trazadone as one of the additional agents to be administered with milnacipran (or its salt). Accordingly, Applicant’s believe that claims 99-128 are not obvious over Loder in view of Hitzig.

Claims 77, 84, 90 and 90-98 stand rejected under 35 U.S.C. § 103(a) as obvious over Loder in view of Hitzig and further in view of WO 00/32178 ("Mueller"). The Examiner asserts, based on these references, that it would have been obvious to treat pain perception using a combination of milnacipran and sibutramine.

Claims 77, 84, 90 and 90-98 have been canceled, rendering this rejection moot. New claims 99-128 do not recite sibutramine as one of the additional agents to be administered with milnacipran (or its salt). Accordingly, Applicant's believe that claims 99-128 are not obvious over Loder in view of Hitzig and Mueller.

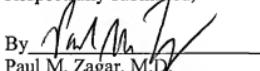
#### IV Conclusion

No new matter has been added by these amendments. In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: December 14, 2007

Respectfully submitted,

By   
Paul M. Zagar, M.D.

Registration No.: 52,392  
DARBY & DARBY P.C.  
P.O. Box 770  
Church Street Station  
New York, New York 10008-0770  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant